



DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 156

[CMS-9898-NC]

RIN 0938-AV14

Request for Information; Essential Health Benefits

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: This request for information (RFI) solicits public comment on issues related to the Essential Health Benefits (EHB) under the Patient Protection and Affordable Care Act (the Affordable Care Act or ACA). CMS is issuing this RFI to gather input from the public regarding a variety of topics related to the coverage of benefits in health plans subject to the EHB requirements of the ACA. These topics include: the description of the EHB, the scope of benefits covered in typical employer plans, the review of EHB, coverage of prescription drugs, and substitution of EHB.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by [Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, refer to file code CMS-9898-NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9898-NC,

P.O. Box 8016,
Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-9898-NC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Leigha Basini, (301) 492-4380, or Rebecca Bucchieri, (301) 492-4341, for general information.

Ken Buerger, (410) 786-1190.

Nathan Caulk, (667) 290-9975.

Nicole Levesque, (667) 290-9974.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual.

CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Section 1301(a)(1)(B) of the Affordable Care Act¹ requires all issuers of qualified health plans (QHPs) to cover the “Essential Health Benefits (EHB) package” described in section 1302(a) of the ACA, which includes coverage of the services described in section 1302(b) of the ACA. Section 2707(a) of the Public Health Service Act (PHS Act) extends the requirement to cover the “EHB package” to non-grandfathered individual and small group health insurance coverage (hereinafter, such plans are referred to as plans subject to EHB requirements), irrespective of whether such coverage is offered through an Exchange.

Section 1302 of the ACA provides for the establishment of this “EHB package” to include coverage of the EHB (as defined by the Secretary), cost-sharing limits, and actuarial value (AV) requirements. Section 1302(b) of the ACA directs the Secretary, in defining the EHB, to ensure that they are equal in scope to the benefits provided under a typical employer plan, and that they include at least the following 10 general categories and the items and services covered within the categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

On December 16, 2011, HHS released a bulletin² that outlined an intended regulatory

¹ The Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted on March 23, 2010. The Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this request for information, the two statutes are referred to collectively as the “Patient Protection and Affordable Care Act,” “Affordable Care Act” or “ACA”.

² The HHS EHB bulletin is available on the CMS website at https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.

approach for defining EHB, including a benchmark-based framework. We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). As implemented in the EHB Rule, for a non-grandfathered individual or small group market health plan to provide the “EHB package,” the health plan must, among other things, provide the benefits in accordance with the State’s EHB-benchmark plan, as described at 45 CFR 156.115. A State’s EHB-benchmark plan serves as a reference plan for the benefits considered as EHB in the State. Section 156.115(a) states that the provision of EHB means that a health plan, among other things, provides benefits that are substantially equal to the State’s EHB-benchmark plan including: covered benefits; limitations on coverage including coverage of benefit amount, duration, and scope; and prescription drug benefits that meet the requirements of § 156.122.³

For plan years 2014 through 2016, each State’s EHB-benchmark plan was based on one of the health plans identified at § 156.100 that was available in the State in 2012, with any missing benefit categories supplemented as specified under § 156.110.⁴ For plan years 2017, 2018, and 2019, each State’s EHB-benchmark plan was based on one of the health plans identified at § 156.100 that was available in the State in 2014, with any missing benefit categories supplemented as specified under § 156.110.

The 2019 Payment Notice final rule, which appeared in the April 17, 2018 **Federal Register** (83 FR 16930), added § 156.111 to provide States with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond. In that final rule, we stated that we believe States should have additional choices with respect to benefits and affordable coverage, and we added § 156.111 to provide additional flexibility for States to select new EHB-

³ An issuer of a plan offering EHB may substitute benefits for those provided in the EHB-benchmark plan pursuant to § 156.115(b).

⁴ As specified by § 156.100(c), for plan years beginning prior to January 1, 2020, if a State did not make an EHB-benchmark selection using the process described in the section, the State’s EHB-benchmark defaulted to the largest plan by enrollment in the largest product by enrollment in the State’s small group market.

benchmark plans starting with the 2020 plan year.⁵ To date, CMS has approved changes to 7 State EHB-benchmark plans under § 156.111.⁶ For each plan year, States that opt not to exercise this flexibility use the same EHB-benchmark plan from the previous plan year. The current EHB-benchmark plans are available on the CMS website at <https://www.cms.gov/CCIIO/Resources/Data-Resources/ehb>.

II. Solicitation of Public Comments

CMS requests comments from all interested parties to gain a better understanding of the coverage of benefits in health plans with respect to the following specific areas:

Benefit Descriptions in EHB-benchmark Plan Documents

The EHB-benchmark plan approach was designed to “allow States to build on coverage that is already widely available, minimize market disruption, and provide consumers with familiar products. This should heighten consumer understanding of plan options and may facilitate consumers’ abilities to make choices that better suit their needs.”⁷ We believe that this approach was largely successful in these regards. At the same time, we are mindful of concerns that this approach creates a patchwork of coverage of EHB, such that any particular benefit may have disparate coverage nationwide across all 51 EHB-benchmark plans.

We are also mindful that the EHB-benchmark plan documents can describe the covered benefits differently, which may create ambiguity in defining the EHB in a particular State. For example, one State’s EHB-benchmark plan may specifically mention coverage of ground, water, and air ambulance, while another State’s EHB-benchmark plan may simply cover “medically necessary transportation” without distinguishing whether such coverage includes ground, water, or air ambulance. As another example, one EHB-benchmark plan may cover “Diagnostic

⁵ Under § 156.111(a), a State may change its EHB-benchmark plan by: (1) selecting the EHB-benchmark plan that another State used for the 2017 plan year; (2) replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same category or categories of benefits from another State’s EHB-benchmark plan used for the 2017 plan year; or (3) otherwise selecting a set of benefits that would become the State’s EHB-benchmark plan.

⁶ Illinois (2020), South Dakota (2021), Michigan (2022), New Mexico (2022), Oregon (2022), Colorado (2023), and Vermont (2024).

⁷ 78 FR 12833, 12860 (February 25, 2013).

radiology services and Imaging studies,” while another EHB-benchmark plan has a more detailed description of covered radiological and imaging benefits: “Benefits are also available for advanced imaging services, which include but are not limited to: CT scan, CTA scan, Magnetic Resonance Imaging (MRI), Magnetic Resonance Angiography (MRA), Magnetic resonance spectroscopy (MRS), Nuclear Cardiology, PET scans, PET/CT Fusion scans, QTC Bone Densitometry, Diagnostic CT Colonography.” Accordingly, some State EHB-benchmark plan documents are well over 100 pages and include these more detailed descriptions of covered benefits and limitations, while other EHB-benchmark plans are only a few dozen pages with shorter, more generalized descriptions of covered benefits and limitations.

The difference in how the benefits are described in the EHB-benchmark plans is not particularly surprising. These plan documents were written by different authors at different times, serving different segments of the population with different health needs, and subjected to different Federal or State requirements. We understand that the authors of the plan documents used as the EHB-benchmark plans may not have anticipated that the language used in that plan document would be used to define the EHB for a State indefinitely. Even now, with States able to change their EHB-benchmark plan by selecting a set of benefits to become the State’s EHB-benchmark plan under § 156.111(a)(3), we believe it may be unreasonable to expect a State to exhaustively describe all covered benefits and limitations in their EHB-benchmark plan document.

Based on our experience and review of the EHB-benchmark plan documents, it is apparent that the more descriptive an EHB-benchmark plan document is, the greater the certainty is that a specific benefit is considered to be an EHB in the State. As a result, it is difficult for States, CMS, and other interested parties to reliably compare the EHB-benchmark plan document from one State to another. This inhibits State and Federal ability to gauge the overall generosity of plans subject to EHB requirements, which makes it more difficult for States to consider

changes to their EHB-benchmark plans under § 156.111(a)(1) and (2).⁸ It also makes it more difficult for CMS to fulfill its statutory obligation at section 1302(b)(4)(G) and (H) of the ACA to periodically review and update the EHB to address gaps in coverage or changes in evidence basis.

To be clear, we do not necessarily believe that this ambiguity in the covered benefits and limitations in the EHB-benchmark plans has resulted in overt consumer harm. For example, based on our discussions with States and a lack of consumer complaints about exclusions or claims denials, plans subject to EHB requirements do not appear to be excluding services that are generally understood to be covered, regardless of their specific inclusion in the relevant EHB-benchmark plan document. Accordingly, we believe that the States have generally proven to be effective enforcers of the EHB requirement in ensuring that benefits are still treated as EHB in instances where the EHB-benchmark plan language is ambiguous or lacking in detail.⁹ We seek public comment on this understanding, including to what extent States may require additional guidance on how to ensure that plans are interpreting the EHB-benchmark plan documents in a manner that provides EHB coverage to consumers, consistent with applicable requirements.

Typical Employer Plans

Section 1302(b)(2)(A) of the ACA requires the scope of the EHB to be equal to the scope of benefits provided under a “typical employer plan.” To implement section 1302(b) of the ACA and the typical employer plan standard, CMS defined EHB based on a benchmark plan approach at § 156.100(a). States were required to select from one of 10 base-benchmark plans, including the largest health plan by enrollment in any of the three largest small group insurance products by enrollment, any of the largest three State employee health benefit plan options by enrollment

⁸ In addition, it inhibits the ability of self-insured plans to gauge the overall scope of items and services included in EHB-benchmark plans for purposes of selecting a definition of EHB to comply with the requirement to limit enrollee cost sharing to the annual limitation on cost sharing and the prohibition of lifetime or annual limits. See 45 CFR 147.126(c) and ACA Implementation FAQ 18 at https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs18.

⁹ CMS has the responsibility to directly enforce the relevant Public Health Service Act provisions with respect to health insurance issuers in the group and individual markets in Missouri, Oklahoma, Texas, and Wyoming.

and generally available to State employees in the State involved, any of the largest three national Federal Employees Health Benefits (FEHB) Program plan options by aggregate enrollment that are offered to all FEHB-eligible Federal employees, or the coverage plan with the largest insured commercial non-Medicaid enrollment offered by a health maintenance organization operating in the State.

In the 2019 Payment Notice, we finalized options at § 156.111 to provide States with greater flexibility to select new EHB-benchmark plans beginning with the 2020 plan year, if they so choose. A State's EHB-benchmark plan must still provide a scope of benefits equal to the scope of benefits provided under a typical employer plan.¹⁰ For plan year 2020 and after, § 156.111(b)(2) defines a typical employer plan as either (1) one of the selecting State's 10 base-benchmark plan options established at § 156.100 from which the State was able to select for the 2017 plan year; or (2) the largest health insurance plan by enrollment in any of the five largest large group health insurance products by enrollment in the selecting State, provided that the plan meets the requirements in § 156.111(b)(2)(i)(B)(1) through (4).

We seek comment on changes in the scope of benefits offered by employer plans since plan year 2014. In particular, we are interested in comments that discuss the relative generosity of the current typical employer plans described at § 156.100(a)(1) through (4) and § 156.111(b)(2)(i)(B), and whether they are reflective of the scope of benefits provided under employer plans offered in more recent plan years, or whether employer plans offered since plan year 2014 are more or less generous. We seek comment on whether there are other employer plans commonly sold in States that are not reflected in the current typical employer plans described at § 156.100(a)(1) through (4) and § 156.111(b)(2)(i)(B). We invite our State partners to elaborate on whether changes in State markets since 2014 may warrant changes to the current definition of a "typical employer plan."

¹⁰ Or greater than the scope of benefits provided under a typical employer plan to the extent any supplementation is required to provide coverage within each EHB category at § 156.110(a).

Review of EHB

Section 1302(b)(4)(G)(i) through (iv) of the ACA require CMS to periodically review the EHB to determine: (1) whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost; (2) whether EHB need to be modified or updated to account for changes in medical evidence or scientific advancement; (3) information on how EHB will be modified to address any such gaps in access or changes in the evidence base; and (4) the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations. In furtherance of this statutory obligation, we seek comment on each of these topics.

Barriers of accessing services due to coverage or cost

First, we seek comment on whether and to what extent consumers enrolled in plans that provide EHB are facing any difficulty accessing needed services due to coverage or cost.

Specifically:

- Are there significant barriers for consumers to access mental health and substance use disorder services, including behavioral health services that are EHB? To what extent has the utilization of telehealth impacted access to the behavioral health services that are EHB, particularly during the COVID-19 pandemic? How could telehealth utilization better address potential gaps in consumer access to EHB for behavioral health services or other health care services?
- What other strategies have plans implemented to broaden access to telehealth services?
- What efforts have plans found effective in controlling costs of EHB? To what extent do plans that provide EHB see increased utilization and higher costs if those efforts are not implemented? What strategies have consumers and providers seen plans implement to reduce utilization and costs, such as use of prior authorization, step therapy, etc.? Are these strategies to reduce utilization and costs applied broadly or are they targeted to a specific area? What, if any, geographic differences have been found in the strategies plans use to reduce utilization and costs

within a State? How are these tools effective or ineffective? To what extent do these tools curb or complicate access to medically necessary care?

Changes in medical evidence and scientific advancement

Second, we seek comment on whether and to what extent the EHB need to be modified or updated to account for changes in medical evidence and scientific advancement. We expect that there have been significant changes in medical evidence and scientific advancement for certain benefits since 2014. For example, after the original EHB-benchmark plans had been selected, silver diamine fluoride, which is an inexpensive treatment that can stop dental caries and is particularly useful for pediatric populations, became available in the U.S.¹¹ Another example of a change in medical evidence is the increased understanding of and reliance on doula services as a cost-effective way to improve maternal and newborn health outcomes.¹² To that end:

- What changes in medical evidence and scientific advancement have occurred since 2014 that are not reflected in the current EHB-benchmark plans? Are there benefits widely covered as EHB that are not supported by current medical evidence?

- Are there other barriers to incorporating changes in medical evidence and scientific advancement into the EHB? How can the EHB better track with changes in medical evidence and scientific advancement? What steps should be taken to address EHB that are not supported by current medical evidence?

We are also interested in how changes in medical evidence or scientific advancement generally could inform CMS' health equity and nondiscrimination efforts with regards to EHB. For example, there may be lack of coverage for treatment informed by scientific advancements in certain areas of health care resulting in a disproportionate impact on consumers, or there may

¹¹ Crystal YO, Niederman R. Evidence-Based Dentistry Update on Silver Diamine Fluoride. *Dent Clin North Am*. 2019 Jan;63(1):45-68. doi: 10.1016/j.cden.2018.08.011. PMID: 30447792; PMCID: PMC6500430. Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6500430/>.

¹² Greiner KS (et al.). The Cost-Effectiveness of Professional Doula Care for a Woman's First Two Births: A Decision Analysis Model. *Journal of Midwifery & Women's Health*. Available at <https://onlinelibrary.wiley.com/doi/full/10.1111/jmwh.12972>.

be new medical evidence indicating certain consumers are encountering specific barriers in accessing certain EHB. To that end:

- How might the EHB adapt to more quickly address pressing public health issues such as public health emergencies (including the opioid and overdose epidemic) and maternal mortality rates (particularly among underserved populations)? For example, what are the barriers for third-parties such as family members or caregivers to obtain naloxone?
- How should the EHB advance health equity by taking into consideration economic, social, racial, or ethnic factors that are relevant to health care access (for example, access to appropriate language services)?
- In what ways could EHB better address health conditions that disproportionately affect underserved populations or large parts of the American population?
- For example, how could EHB address nutrition-related health conditions for the American population? How has the medical evidence regarding nutrition-related health conditions changed since 2014? How can EHB better improve nutrition-related health outcomes for the populations that are most likely to benefit from coverage of nutrition-related care, such as people with diabetes?
- What strategies are issuers and plan sponsors using to improve nutritional-related health outcomes for enrollees, and what strategies could they implement? To what extent have issuers and plan sponsors designed their own strategies as compared to relying on existing models (for example, the evidence-based National Diabetes Prevention Program¹³)?
- How have scientific advancements and new delivery mechanisms impacted the content of nutrition-related care, provider delivery, access to care, and how plan sponsors and issuers manage it?

Addressing gaps in coverage

¹³ National Diabetes Prevention Program. Available at <https://www.cdc.gov/diabetes/prevention/index.html>.

Third, we seek comment on how the EHB could be modified to address any gaps in coverage or scope of benefits. Specifically:

- Are there examples of benefits that are essential to maintaining health, including behavioral health, that are insufficiently covered as EHB but that are routinely covered by other specific health plans or programs, such as employer-sponsored plans, Medicare, and Medicaid?

To what extent does the EHB cover screening, consultative, and treatment modalities that supports the integration of both mental health and substance use disorder services into primary care?

- Many State base-benchmark plan documents do not include specific coverage for habilitative services. To comply with section 1302(b)(1)(G) of the ACA, these States supplement the base-benchmark plans with habilitative services pursuant to § 156.110(f) by determining which services in that category will be covered as EHB.¹⁴ In our experience, State supplementation of habilitative services is inconsistent. We are interested in comments on which habilitative services are currently covered as EHB, and whether further definition is needed in general to clarify the covered benefits. We also seek comment on whether EHB-benchmark plans' current coverage and limits regarding habilitative services, which were primarily based on coverage for rehabilitative purposes, are sufficient and in line with current clinical guidelines for treatment of developmental disabilities.

- Is there sufficient coverage as EHB of emergency behavioral health services, including mobile crisis care and stabilization services? To what extent is there sufficient coverage as EHB for other levels of care, such as for crisis prevention and care coordination for behavioral health services? To what extent do plans that provide EHB include peer and recovery support for behavioral health services?

¹⁴ 45 CFR 156.110(f) states: "If the base-benchmark plan does not include coverage for habilitative services, the State may determine which services are included in that category."

- Aside from the required preventive services for children,¹⁵ and the identification in section 1302(b)(1)(J) of the ACA for “[p]ediatric services, including oral and vision care” as one of the 10 categories of EHB, the EHB-benchmark plans largely do not differentiate between benefits for adults and benefits for children. Are there differences between adult and pediatric benefits and those populations’ needs such that further delineation of pediatric benefits is warranted? How does the scope of health benefits for children compare between employer-sponsored group health plans and States’ separate Children’s Health Insurance Program plans?

- To what extent could EHB better address any gaps in coverage for those with chronic and lifelong conditions?

- How can CMS balance State flexibility (as States are generally the primary enforcers of EHB) with the statutory requirement to ensure sufficient coverage for a diverse population, including those living in rural areas who may have limited provider types available?

- What other strategies could be implemented to modify EHB to address gaps in coverage or changes in the evidence base?

Actuarial and cost-sharing limitations

Lastly, we recognize that any efforts to revise the EHB to change the benefits covered as EHB have the potential to impact costs and the ability of plans to meet the actuarial and cost-sharing limitations under section 1302 of the ACA. We invite comments that address the ability of plans subject to EHB requirements to conform benefit designs to these requirements.

Coverage of Prescription Drugs as EHB

As finalized in the EHB Rule, plans subject to EHB requirements must comply with § 156.122(a)(1) to cover at least the same number of prescription drugs in every United States Pharmacopeia (USP) category and class as covered by the State’s EHB-benchmark plan, or one drug in every category and class, whichever is greater. We also stated that plans could exceed the minimum number of drugs required to be covered and that additional drugs would still be

¹⁵ See generally 45 CFR 147.130(a)(1).

considered EHB. In that final rule,¹⁶ we chose to use the USP Model Guidelines Version 5.0 (USP Guidelines) to classify the drugs required to be covered as EHB under § 156.122(a)(1). In so doing, we noted that “[w]hile there was concern among commenters on the use of USP as the system, there was no universal system identified as a potential alternative. We chose the current version USP Model Guidelines (version 5) because it is publicly available and many pharmacy benefit managers are familiar with it. We believe the USP model best fits the needs for the years 2014 and 2015 during the transitional EHB policy.”¹⁷ CMS and the USP developed the USP Guidelines in 2004 to implement the Medicare Part D Prescription Drug Program.¹⁸ Section 1860D-2(e) of the Social Security Act (the Act) defines a “covered part D drug” for purposes of the Medicare Part D program, and the statutory definition excludes certain drugs,¹⁹ such as drugs for anorexia, weight loss, or weight gain.²⁰ Consequently, the USP Guidelines do not include categories and classes to classify these excluded drugs; as a result, these drugs are not required to be covered as EHB under § 156.122(a)(1). However, certain types of weight management drugs may still be covered in a health plan as EHB but under a different drug category (for example, weight management drugs classified and covered under the category for central nervous system drugs). Additionally, nothing prevents plans from voluntarily covering these drugs as EHB. However, the variation in classification for these drugs leads to potential coverage gaps for consumers.

In the 2016 Payment Notice,²¹ we solicited comments regarding whether to replace the USP Guidelines with a standard based on the American Hospital Formulary Service (AHFS) or

¹⁶ 78 FR at 12846.

¹⁷ 78 FR at 12845-12846.

¹⁸ USP Medicare Model Guidelines. Available at <https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines>.

¹⁹ See section 1860D-2(e)(2) of the Act.

²⁰ See section 1927(d)(2) of the Act. List of Drugs Subject to Restriction include drugs used for anorexia, weight loss, weight gain, fertility, cosmetic purposes or hair growth, symptomatic relief of cough and colds, smoking cessation, prescription vitamins and mineral products, nonprescription drugs, certain covered outpatient drugs, barbiturates, benzodiazepines, and drugs for the treatment of sexual or erectile dysfunction.

²¹ 2016 Final Payment Notice: Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 FR 10750, 10813 (February 27, 2015). Available at <https://www.govinfo.gov/content/pkg/FR-2015-02-27/pdf/2015-03751.pdf>.

another drug classification system. CMS ultimately decided to retain the USP Guidelines classification system because “[i]ssuers have already developed 2 years of formularies based on it, States have already developed systems to review those formularies, and interested parties are familiar with the system. Thus, while AHFS had the benefit of being updated more frequently and incorporating a broader set of classes and subclasses, commenters did not uniformly support its use because of several issues, including a lack of transparency, the need to supplement certain classes when compared with USP, and the complexity of the AHFS system.”²²

In 2017, the USP developed a second drug classification system, the USP Drug Classification (DC), an independent drug classification system “developed in response to input from interested parties that it would be helpful to have a classification system beyond the Medicare Model Guidelines (MMG) to assist with formulary support outside of Medicare Part D.”²³ We note that USP DC system has many features that may be beneficial to consumers and meet evolving public health challenges. The USP DC system provides examples of common U.S. outpatient drugs and is updated annually.

We recognize the potential challenges of switching drug classification systems for EHB. We reviewed public comments for the proposed 2016 Payment Notice related to the AHFS system and recognize the concerns of lack of transparency or the need to supplement certain classes when compared with USP Guidelines, and the complexity of the AHFS system. However, we note that other drug classification systems, such as USP DC or others, may provide greater benefit for consumers. In addition, we note that switching to the USP DC system may not be as disruptive as switching to AHFS due to the unique features of the USP DC system such as applicability and readiness of the system. We seek public comment to confirm or further expand on our understanding of the risks and benefits of replacing the current USP Guidelines with a different drug classification system.

²² *Id.*

²³ USP Drug Classification. Available at <https://www.usp.org/health-quality-safety/usp-drug-classification-system>.

We seek comment on whether CMS should consider using an alternative prescription drug classification standard for defining the EHB prescription drug category, such as the USP DC or others, in the future.

Substitution of EHB

In the EHB Rule, we added § 156.115(b) so that health plans may substitute benefits for those provided in the EHB-benchmark plan, provided that the substitution is actuarially equivalent and the benefit is not a prescription drug benefit. We added this flexibility “to provide greater choice to consumers, and promote plan innovation through coverage and design options.”²⁴ In the 2019 Payment Notice, we modified paragraph (b)(1)(ii) to allow States to permit issuers to substitute benefits within the same EHB category *and* between EHB categories, as long as the substituted benefit is actuarially equivalent to the benefit being replaced and is not a prescription drug benefit.²⁵ In the 2023 Payment Notice²⁶, we amended § 156.115(b)(2) to withdraw the flexibility for health plans to substitute benefits between different EHB categories in response to public comments that the practice could lead to adverse selection and discrimination by allowing health plans to remove benefits needed by people with significant health needs and substitute them with benefits meant to attract healthier enrollees.

Ever since we implemented the ability for the substitution of EHB, we have received substantial feedback urging CMS to remove the ability for health plans to substitute EHB because of concerns that the practice could lead to discrimination or negative health outcomes. Others have expressed concerns that allowing such substitution makes it difficult for regulators to ensure that plans are actually covering the EHB and that substitution could be confusing for consumers. However, we have also received feedback that the option of substitution may allow plans flexibility in benefit design to address changing public health concerns and cover innovations in health care as EHB.

²⁴ 78 FR 12833, 12844 (February 25, 2013).

²⁵ 83 FR 16930, 16930 (April 17, 2018).

²⁶ 87 FR 27208 (May 6, 2022).

To date, CMS has not received any information that any health plan has ever substituted an EHB using this flexibility. While States are not required to notify CMS when health plans substitute benefits under § 156.115(b), any health plan seeking certification as a QHP on a Federally-facilitated Exchange (FFE) may indicate, at its option, whether a particular benefit is substituted in its QHP application. CMS, as operator of the FFEs, has not received any QHP application that indicates that any QHP issuer on an FFE has substituted a benefit in this manner. We seek comment regarding the extent to which health plans have ever substituted EHB under § 156.115.

To the extent the substitution of EHB is not widely used by health plans, we seek comment on how we might revisit our rules regarding the substitution of EHB in future rulemaking so that consumers have access to health plans that can better address changing public health concerns or innovation in health care. Alternatively, we seek comment regarding whether health plans should not be permitted to substitute EHB within the same EHB category.

III. Collection of Information Requirements

Please note, this is a RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through this RFI and will not accept unsolicited

proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. CMS notes that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, CMS will not respond to questions about the policy issues raised in this RFI.

CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. These communications would be for the sole purpose of clarifying Statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Responders should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, CMS may publicly post the public comments received, or a summary of those public comments.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 14, 2022.

Dated: November 29, 2022.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

[FR Doc. 2022-26282 Filed: 11/30/2022 4:15 pm; Publication Date: 12/2/2022]